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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,865	10/16/2003	Walter Schubert	S159 1030.1	7435
7590 09/19/2008 WOMBLE CARLYLE SANDRIDGE & RICE P.O. Box 7037 Atlanta, GA 30357-0037				
EXAMINER MOSS, KERI A				
ART UNIT 1797		PAPER NUMBER		
MAIL DATE 09/19/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/686,865

**Applicant(s)**

SCHUBERT, WALTER

**Examiner**

KERI A. MOSS

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2008 has been entered.
2. Claims 1-10 and 21 are pending.

***Response to Amendment***

3. The objection to claim 2 has been withdrawn in light of applicants' amendments and arguments.
4. Previous rejections of claims 1-10 under 35 USC 102(b) as anticipated by Ryan et al. and Mansfeld et al. have been withdrawn in light of applicants' amendments and arguments.

***Claim Rejections - 35 USC § 102***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims **1-10** are rejected under 35 U.S.C. 102 (b) as being anticipated by Wahle et al. (USP 6,242,220).

Wahle discloses a method for preparing biological samples for analysis, comprising placing the biological sample on a two-dimensional support, applying protein-precipitating or denaturing first solution L1 to the biological sample on the support at a first temperature for a predetermined first time period (column 10 lines 8-15); applying a protein-precipitating or denaturing solution L2 to the biological sample on the support at a second temperature for a predetermined second time period on the support, with T2 being lower than T1 (column 10 lines 15-21); and then drying the sample on the support (column 10 lines 16-17). An additional air drying of the sample takes place between process steps b) and c) (column 10 lines 9-10). The biological sample is a cell sample (column 9). Solution L1 is a solution with a critical pH value and solution L2 is a salt solution. T1 covers a temperature range of -10 degrees Celsius to 60 degrees Celsius (column 10 lines 8-15). After step d), the biological samples are subjected to a protein-chemical separation method (column 10 lines 22-30).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims **1-10 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton (USP 5,436,129) in view of Wahle et al. (USP 6,242,220). Stapleton discloses a method for preparing biological samples for analysis (Example 1) comprising applying the sample to a slide, applying solutions to the sample to denature the protein (column 18 lines 36-50), changing the temperature of the sample (column 17 lines 27-45) and drying the sample between treatments (column 17 lines 24-26; column 18 lines 14-17; column 18 lines 49-50).

Stapleton does not expressly teach applying the protein denaturing solution at one temperature, then leaving the solution while lowering the temperature. Wahle is analogous art as it also discloses a method of preparing a biological sample for analysis. Wahle discloses a method for preparing biological samples for analysis, comprising placing the biological sample on a two-dimensional support, applying protein-precipitating or denaturing first solution L1 to the biological sample on the support at a first temperature for a predetermined first time period (column 10 lines 8-15); applying a protein-precipitating or denaturing solution L2 to the biological sample on the support at a second temperature for a predetermined second time period on the

support, with T2 being lower than T1 (column 10 lines 15-21); and then drying the sample on the support (column 10 lines 16-17). An additional air drying of the sample takes place between process steps b) and c) (column 10 lines 9-10). The biological sample is a cell sample (column 9). Solution L1 is a solution with a critical pH value and solution L2 is a salt solution. T1 covers a temperature range of -10 degrees Celsius to 60 degrees Celsius (column 10 lines 8-15). After step d), the biological samples are subjected to a protein-chemical separation method (column 10 lines 22-30).

An advantage of the Wahle protocol is that it is available in kit form, thus making it faster and easier to conduct the sample preparation (Example 1). Thus, it would have been obvious to apply the protocol of Wahle to the slide preparation of Stapleton in order to gain the advantages of shorter preparation time.

### ***Response to Arguments***

10. Applicant's arguments, see Request for Continued Examination, filed 8/18/08, with respect to the rejection(s) of claim(s) 1-10 under Ryan et al. and Mansfeld et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wahle et al. as well as in view of Stapleton (USP 5,436,129) and further in view of Wahle et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/  
Examiner, Art Unit 1797

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797